

NEWS RELEASE



OFFICE OF THE UNITED STATES ATTORNEY SOUTHERN DISTRICT OF CALIFORNIA

San Diego, California

*United States Attorney
Laura E. Duffy*

For Further Information, Contact: Assistant U.S. Attorney Melanie Pierson (619) 546-7976

For Immediate Release

LOCAL ONCOLOGY PRACTICE SENTENCED TO PAY MILLIONS FOR MEDICARE FRAUD

NEWS RELEASE SUMMARY - JUNE 28, 2013

The La Jolla oncology practice known as Joel I. Bernstein, M.D., Inc. was sentenced today to pay a \$500,000 fine, forfeit \$1.2 million and make restitution to Medicare in the amount of \$1.7 million for purchasing unapproved foreign cancer drugs and billing Medicare as if the drugs were legitimate.

The sentence was handed down by U.S. District Judge Cathy A. Bencivengo following the corporation's guilty plea to health care fraud in January. The practice was also sentenced to a year of probation, which means it must allow Probation officers to scrutinize finances, submit to office searches and prepare a compliance program to avoid such problems in the future.

In pleading guilty, the practice admitted that it had purchased \$3.4 million of foreign cancer drugs, knowing they had not been approved by the U.S. Food and Drug Administration for use in the United States. From 2007 to 2011, Bernstein's office purchased these drugs for significantly less than market value in the U.S., and then submitted claims to Medicare at the full reimbursement

price. To conceal the scheme, the office fraudulently used Medicare reimbursement codes for approved cancer drugs, as Medicare does not pay for unapproved drugs.

The drugs purchased by the corporation were meant for markets outside the United States and contained the same active ingredients as drugs sold in the U.S. under the brand names Abraxane®, Alimta®, Aloxi®, Boniva®, Eloxatin®, Gemzar®, Neulasta®, Rituxan®, Taxotere®, Venofer® and Zometa®).

The practice has admitted that it was aware that the drugs were intended for markets other than the United States and were not the drugs approved by the FDA for use in the United States because: (a) the packaging and shipping documents indicated that drugs were shipped to the office from outside the United States; (b) many of the invoices identified the origin of the drugs and intended markets for the drugs as countries other than the United States; (c) the labels did not bear the “Rx Only” language required by the FDA; (d) the labels did not bear the National Drug Code (NDC) numbers found on the versions of the drugs intended for the U.S. market; (e) many of the labels had information in foreign languages; (f) the drugs were purchased at a substantial discount; (g) the packing slips indicated that the drugs came from the United Kingdom; and (h) the office had received a Notice from the FDA in October, 2008, that a shipment of drugs had been detained because the drugs were unapproved.

Medicare provides reimbursement only for drugs approved by the Food and Drug Administration (FDA) for use in the United States. The practice admitted that it knowingly submitted claims for payment to Medicare using the reimbursement codes for the U.S. approved drugs, falsely representing that the drugs were those approved by the FDA for use on patients in the United States.

The defendant acknowledged that between January of 2007, and May of 2011, the practice received \$1.7 million in reimbursement from Medicare as a result of this fraudulent scheme. The practice was ordered to forfeit \$1.2 million, which was the amount of gross proceeds received by the defendant solely related to the drugs.

In a related False Claims Act lawsuit filed by the United States, Dr. Bernstein and his medical practice paid in excess of \$2.2 million to settle allegations that they submitted false claims to the Medicare program. The corporation was allowed to apply that sum toward the amount owed in the criminal restitution to Medicare.

Dr. Bernstein himself also pleaded guilty to a misdemeanor charge of Introducing Unapproved Drugs into Interstate Commerce. In pleading guilty, Dr. Bernstein admitted that on July 8, 2010, he purchased the prescription drug Mabthera (intended for market in Turkey and shipped from a source in Canada) and administered it to patients. Bernstein further acknowledged that the drug Mabthera is not approved by the Food and Drug Administration for use in the United States. Rituxin®, a product with the same active ingredient, is approved by the Food and Drug Administration for use in the United States.

Dr. Bernstein was released on a \$10,000 personal surety bond and is scheduled to be sentenced on July 2, 2013 at 2:00 p.m.

DEFENDANT

Criminal Case No. 13cr0119-CAB

Joel I. Bernstein, M.D., Inc.

Date of Incorporation: 1998

La Jolla, California

SUMMARY OF CHARGES

Health Care Fraud, in violation of Title 18, United States Code, Sections 1347 and 2

Maximum Penalty for a Corporation: \$500,000 fine, \$400 special assessment.

AGENCIES

Food and Drug Administration, Office of Criminal Investigations

Federal Bureau of Investigation

